K062481

OCT 16 2006

EXHIBIT 2

510(k) Summary

Pishon High Tech Co., Ltd
2nd Floor, Moeller building 403-1, Daebang-dong, Dongjak-gu,
Seoul, 156-020, Korea
Phone: 82-2-826-1750
Fax: 82-2-826-1724

July 12, 2006

Contact: Y.Y. Park, Managing Director

1. **Identification of the Device:**
   Proprietary-Trade Name: SERENO Electronic Stethoscope
   Classification Name: Electronic Stethoscope, Product code DQD
   Common/Usual Name: Electronic Stethoscope

2. **Equivalent legally marketed devices** 3M™ Littmann™ Electronic Stethoscope (K003723), JABES Electronic stethoscope (k031446)

3. **Indications for Use (intended use)** The SERENO Electronic Stethoscope is intended for medical diagnostic purposes only. It can be used for the amplification of heart, lung and other body sounds with the use of selective frequency and can be used on any patient undergoing a physical assessment.

4. **Description of the Device:** The SERENO electronic stethoscope is intended for use as a diagnostic aid in patient diagnosis and monitoring. The SERENO electronic stethoscope amplifies sounds up to 20 times bigger than ordinary acoustic stethoscope in a broad frequency range including a range higher than the traditional diaphragm mode. It looks similar to the traditional stethoscope including parts like a probe head, binaural pipes and ear tips. It has four (4) buttons on the top of the chest set (opposite to the probe). Each of the buttons has a function of controlling the modes, volume up/down and power on/off. As an electronic stethoscope, it needs two (2) batteries (AAA type, 1.5V) to operate. The stethoscope has automatic power off function for longer battery life and has a LCD display to show volume level, frequency mode and low battery indicator. With the enclosed audio cable, utilizing a personal computer, the user can store sound signals in the PC and transmit diagnosis data via e-mail. This stethoscope is a stand-alone unit, has no software and operates using an analog audio system with a digital timer for power saving and a digital control for the volume and the filter mode selection. It can be connected to audio input of a sound card in a computer to use the PC software functions. However, the software does not operate nor control the stethoscope in any manner. In fact, the stethoscope's audio output can be connected to any ordinary audio equipment such as a cassette recorder, a hi-fi audio component and portable audio..

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and user testing indicates that the new device is as safe and effective as the predicate devices.

6. Substantial Equivalence Chart

Device name	Predicate Devices		New Device
	3M Littmann Electronic stethoscope, Model 4000(K003723)	JABES electronic stethoscope (K031446)	SERENO electronic stethoscope
Classification Name	Electronic Stethoscope	Electronic Stethoscope	Electronic Stethoscope
Applicant	3M	GS Technology Co., Ltd	Pishon High Tech Co., Ltd
Frequency Response Mode	Bell(20-200Hz), Diaphragm(100-500Hz) Extended range: (20-1,000Hz)	Bell(20-500Hz), Diaphragm(200-800Hz) Extended range: (20-1,000Hz	Bell(20-450Hz), Diaphragm(200-1,200Hz) Extended range: (20-1,500Hz)
Amplification	Up to 18times amplification	Up to 18times amplification	Up to 20 times amplification
Display heart rate	Yes	No	No
Permits data transfer of stored digital signal to IBM-Compatible PC	Yes	No	No
Volume control	8 Steps Volume control	12 Steps Volume control	12 Steps Volume control
Energy source	Two(2) AAA alkaline batteries	Two(2) AAA alkaline batteries	Two(2) AAA alkaline batteries
Manual On/Off button Automatic shut-off by electronics	Yes	Yes	Yes
Low Battery Indicator	Yes	Yes	Yes

7. Conclusion

After analyzing bench, electrical safety, EMC, and user testing data, it is the conclusion of Pishon High Tech Co., Ltd., that the SERENO Electronic is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2006

Pishon High Tech Co., LTD
c/o Mr. Daniel Kamm, P.E.
Regulatory Engineer
PO Box 7007
Deerfield, IL 60015

Re: K062481
Trade Name: Sereno Electronic Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: August 22, 2006
Received: August 24, 2006

Dear Mr. Kamm:

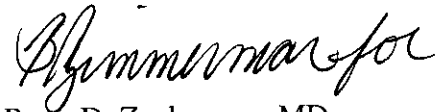
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062481

Device Name: Electronic stethoscope (Model: SERENO)

Indications for Use: The SERENO Electronic Stethoscope is intended for medical diagnostic purposes only. It can be used for the amplification of heart, lung and other body sounds with the use of selective frequency and can be used on any patient undergoing a physical assessment.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062481